

Please type a plus sign (+) inside this box → ☐



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	09/757,688
				Filing Date	January 11, 2001
				First Named Inventor	Wolfgang HEIL et al.
				Group Art Unit	1615
				Examiner Name	L.S. Channavajjala
Sheet	1	of	1	Attorney Docket Number	PLOVIN-2A

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
<i>[initials]</i>		5,534,270		De Castro	7/9/1996

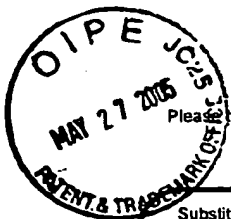
FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
<i>[initials]</i>		CA	2 188 907			4/29/1997		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>[initials]</i>		International Preliminary Examination Report dated 11/29/2001	
<i>[initials]</i>		Remington 2, Farmacia, 17 edicion, Editorial Medica, Panamericana	
<i>[initials]</i>		S. Budavari, et al., "The Merck Index", Merck & Co., Inc., Whitehouse Station, NJ (1996)	
		P. Giunchedi et al., "Spray-drying as a preparation method of microparticulate drug delivery systems: an overview," STP Pharma Sciences 5 (4) 276-290 (1995)	
		J. Broadhead, et al., "The Spray Drying of Pharmaceuticals", Drug Development and Industrial Pharmacy, 18 (11&12), pgs. 1169-1206 (1992)	
		P. Muhn et al., "Drospirenone: A Novel Progestogen with Antimineralocorticoid and Antiandrogenic Activity", Pharmacological Characterization IN animal Models (1995), pgs. 99-110	
		"Letters to the Editor", Gynecol Endocrinol 200, 14:476-478	
		J.W. Tack, "Invitation To the Doctoral Candidates' Colloquium", dated 2-5-1998	
		N. Sattar, et al., "Reproductive Endocrinology Lipoprotein Subfraction Changes in Normal Pregnancy: Threshold Effect of Plasma Triglyceride on Appearance of Small, Dense Low Density Lipoprotein", "The Journal of Clinical Endocrinology & Metabolism Vol. 82, No. 8 2483-2491 (1997)	
<i>[initials]</i>		Letter dated 7-7-2004 re: CHLE Patent Appln. No. 2353-20000 filed 8-30-2000	
<i>[initials]</i>		Opposition to a European Patent Office, Patent No. 1 214 076	
<i>[initials]</i>		CA 136:172763, "Method for preparing an oral formulation containing acid-sensitive drugs, Hsiao, et al.	
<i>[initials]</i>		CA 129:235662, "Stabilization of acid sensitive benzimidazoles with amino acid/cyclodextrin combinations", Klokkeers, et al.	

Examiner Signature	<i>L. Channavajjala</i>	Date Considered	<i>5-23-05</i>
--------------------	-------------------------	-----------------	----------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 15 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.



Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

1

Complete if Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala
Attorney Docket Number	PLOVIN-2A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		L. Lachman et al., "The Theory and Practice of Industrial Pharmacy", Lea & Febiger, Phila. (1970) pgs. 104-108	
		English-language translation of K. H. Bauer et al. article 1993	
		English-language translation of W.A. Ritschel, et al., "The Tablet - Manual on Development, Production and Quality Control", Editio Cantor Verlag Aulendorf 2002	
		English-language translation of P. H. List, et al. article, "Pharmacology - A Testbook for Pharmacists", Wissenschaftliche Verlagsgesellschaft mbH Stuttgart (1980)	
		English-language translation of R. Voigt et al. article, "Pharmaceutical Technology - For Study and Professional Reference", Ullstein Mosby 1993	

Examiner
Signature

L. Channavajjala

Date
Considered

7/25/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box →

+

PTO/SB/08A (08-00)

Approved for use through 10/31/2002 OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1448A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known:

Application Number	08/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL
Group Art Unit	1615
Examiner Name	San-ming Hui
Attorney Docket Number	PLOVIN-2A

U.S. PATENT DOCUMENTS

Examiner initials*	Cite No.†	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code* (if known)		
		6,787,531		Hilman et al.	9/7/2004

FOREIGN PATENT DOCUMENTS

Examiner initials*	Cite No.†	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Page, Column, Lines, Figure Reference, Paragraph or Relevant Portion Appears	T*
		Office‡	Number*				

NON PATENT LITERATURE DOCUMENTS

Examiner initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (e.g., magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume/issue number(s), publisher, city and/or country where published	T*
		Notice of Allowability with Response for Allowance from Prosecution of U.S. Patent 6,787,531	

Examiner
Signature

L. Channavayale

Date
Considered

7/28/05

EXAMINER: Initial if reference considered, whether or not citation is in conformity with MPEP 609. Draw line through citation if not in conformity, and not considered. Include copy of this to co with new communication to applicant.

* Unique citation data, given number. * See attached kinds of U.S. Patent Documents. * Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). * For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. * Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 10 if possible. * Applicant is to place a check mark here if English language translation is attached.

BEST AVAILABLE COPY



Please type a plus sign (+) inside this box →

+

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala
Attorney Docket Number	PLOVIN-2A

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ANDA Notification by Barr Laboratories (14 pgs.)	

Examiner
Signature

L. Channavajjala

Date
Considered

7/20/05

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box → ☐



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1448A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known		
				Application Number	09/757,688	
Sheet		1	of	1	Attorney Docket Number	PLOVIN-2A
		Filing Date	January 11, 2001			
		First Named Inventor	Wolfgang HEIL et al.			
		Group Art Unit	1615			
		Examiner Name	L.S. Channavajjala			

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
✓		2,243,887		Serini et al.	6/3/1941
✓		5,382,434		de Haan et al.	1/17/1995
✓		4,900,734		Maxson et al.	2/13/1990
✓		4,826,831		Plunkett et al.	5/2/1989
✓		4,196,188		Besins	4/1/1980
✓		4,927,816		Ester	5/22/1990

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
✓		EP-0 461 290 12/18/1991 (abstract) attached	
✓		Chaumeil, J.C., "Micronization: A Method of Improving the Bioavailability of Poorly Soluble Drugs", Meth. Find. Exp. Clin. Pharmacol., 1998, pgs. 211-215.	
✓		McInnes, G.T., et al., "Effect of micronization on the bioavailability and pharmacologic activity of spironolactone", Journal of Clinical Pharmacology, 1982; 22:410-417.	
✓		DeVilliers, Melgardt M., "Influence of cohesive properties of micronized drug powders on particle size analysis", Journal of Pharm. & Biomedical Analysis, Vol. 13, No. 3, pgs. 191-198, (1995).	
✓		Fotherby, K., "Bioavailability of Orally Administered Sex Steroids Used in Oral, Contraception and Hormone Replacement Therapy", Elsevier Science, Inc., 1996; pgs. 59-69.	
✓		English-language description from Chile attorney of Opposition in Chile to Chile Application No. 2353-2000	

Examiner Signature	L. Channavajjala	Date Considered	5/23/05
--------------------	------------------	-----------------	---------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

Please type a plus sign (+) inside this box:

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/757,688
				Filing Date	January 11, 2001
				First Named Inventor	Wolfgang HEIL et al.
				Group Art Unit	1615
				Examiner Name	L.S. Channavajjala
				Attorney Docket Number	PLOVIN-2A
Sheet	1	of	1		

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code* (if known)		

FOREIGN PATENT DOCUMENTS

[illegible]

NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner Signature	L. Channavajjala	Date Considered	5/23/05
-----------------------	------------------	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.